ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

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July 14, 2004

Department of Health and Human Services
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

Re: Solicitation of Comments on Stimulating Innovation in Medical Technologies (Docket No. 2004S-0233)

Ethicon Endo-Surgery, Inc., a Johnson & Johnson Company, is the world leader in the development, manufacturing, and distribution of medical devices for minimally invasive and traditional surgical procedures. We appreciate the opportunity to comment on how to stimulate innovation in medical technologies. We agree with you that recent advances in basic sciences have created the potential for the development of innovative medical technologies that can provide new hope and better quality of life for many Americans – the key is making sure that all patients have access to these life saving technologies.

We understand and support the work CMS is doing to help the speed of access to these new technologies with novel ways to better coordinate coverage, payment, and coding for a timely reimbursement process. There is an issue with the current hospital outpatient prospective payment system criteria that impacts access to innovative new medical devices and technology.

A medical device, in order to be granted a new pass-through criteria, must, among other criteria, be "**surgically implanted or inserted** whether or not the device remains with the patient when the patient is released from the hospital." (65 FR 47670; the regulatory changes in that rule are compiled at 42 CFR 419.43).

It appears that the term "surgically implanted or inserted" has been interpreted by CMS to mean that a device must be implanted or inserted through an open surgical incision to meet the pass-through eligibility criteria. Some devices that are implanted through less invasive means - through existing natural orifices, rather than through surgical incisions - are being denied "new category" status under the Medicare OPPS pass-through program based on this criteria alone.

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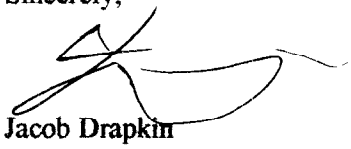
We understand that this policy may have been adopted at the beginning of the device pass-through program, when a multitude of devices were qualifying for the program. However, now that the number of new categories has lessened to a more manageable number, we see no rationale for denying incremental reimbursement to new and innovative devices simply because they are not surgically inserted through a more invasive method. It would be unfortunate if a hospital had the choice between two medical devices -- one inserted surgically through an open incision and one inserted through a natural orifice -- that accomplished similar medical outcomes, yet the hospital chose the more invasive open incision technology simply because of a reimbursement rule.

Medical device technology is rapidly moving toward less invasive approaches to secure the same if not better outcomes. Many of these technologies move inpatient procedures to the outpatient setting of care, have less pain and faster recovery, and can potentially reduce overall health care costs but are not recognized in the current medical device criteria because they go through a natural orifice.

We are concerned that the current CMS interpretation on "surgically implanted or inserted" has and will continue to limit Medicare beneficiary access to innovative and less invasive technologies -- especially in the areas of women's health, colorectal, and gastro-intestinal procedures. As medical technology continues to move toward less invasive approaches to secure the same and even better outcomes, we suggest that CMS revise their reimbursement rules accordingly. If the implantable device meets the other OPPS pass-through criteria, it should not be denied pass-through status simply because a surgical incision is not required for implantation or insertion.

Many innovative medical devices have been denied coverage in the OPPS site-of-care which impacts access to the Medicare beneficiary and the development of other less invasive technologies. To assist with the Roadmap initiative it will be important to modify the existing OPPS criteria and recognize the true value of less invasive technologies. We are hopeful that CMS opens this issue up for comment in the proposed rule.

Sincerely,



Jacob Drapkin